Endoscopy
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We are

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EXHIBIT F

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Levelert II Fluid Level Sensor
Date Prepared: January 16, 2006

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810 USA

B. Company Contact

Janice Haselton
Sr. Regulatory Affairs Specialist
Phone: (978)749-1494
Fax: (978)749-1443

C. Device Name

Trade Name:	Levelert II
Common Name:	Electronic Monitor
Classification Name:	Monitor, Electric for Gravity Flow Infusion Systems

D. Predicate Devices

The predicate device for the Levelert II is the current Smith & Nephew Dyonics Levelert System cleared in K912453.

E. Description of Device

The Levelert II is a irrigation fluid bag level sensing device designed to provide the user with fluid level feedback at pre-determined values. The pre-determined values are selected by the user. The Levelert II is a stand-alone DC battery powered, non-rechargeable device that is used in arthroscopic procedures.

F. Intended Use

The Smith & Nephew Levelert II Fluid Level Sensor is intended to weigh a bag of irrigation fluid and signal operating room personnel when a pre-determined amount of fluid remains.

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G. Comparison of Technological Characteristics

The Levelert II has the same Indications for Use as the predicate device, utilizes the same operating principle, incorporates the same basic design, and is manufactured under a Quality System.

The differences between the Dyonics Levelert System and the Levelert II are the additional of a battery to power the device instead of an external power supply, the use of a load cell instead of a spring loaded circuit design, dome switches instead of an adjusting knob and incorporating the microprocessor internally instead of externally connecting to one.

H. Summary Performance Data

The performance testing, EMI/EMC testing, UL Safety testing and the software verification and validation conducted on the Levelert II demonstrates substantial equivalence to the Dyonics Levelert System cleared in K912453. The testing also demonstrates that the differences in the new device and the predicate device do not raise any new issues of safety and efficacy and that the Levelert II performs as well as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2006

Ms. Janice Haselton
Senior Regulatory Affairs Specialist
Smith & Nephew, Incorporated
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K060123
Trade/Device Name: Levelert II Fluid Level Sensor
Regulation Number: 21 CFR 880.2420
Regulation Name: Electronic Monitor for Gravity Flow Infusion Systems
Regulatory Class: II
Product Code: FLN
Dated: January 16, 2006
Received: January 18, 2006

Dear Ms. Haselton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060123

Device Name: Levelert II Fluid Level Sensor

Indications For Use:

The Smith & Nephew LEVELERT II Fluid Level Sensor is intended to weigh a bag of irrigation fluid and signal operating room personnel when a pre-determined amount of fluid remains.

Prescription Use ___x___ AND/OR Over-The-Counter Use _

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]

[illegible] Division of General Hospital,
[illegible] Dental Devices

[illegible] K964123